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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,750	03/21/2006	Taku Demura	P29533	3329

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EXAMINER
WOLLENBERGER, LOUIS V

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
06/10/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,750	DEMURA ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5,6,8-10 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,11-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/12/2006; 2/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claim(s) 1-4, 7, 11-15, 17-20, drawn to a cassette construct for preparing an inverted repeat sequence, and to plasmid, expression vectors, and host cells thereof in the reply filed on 4/22/2009 is acknowledged. The traversal is on the ground(s) there would be no burden to search and examine Groups I and II together. This is not found persuasive because burden is not a factor for consideration of Unity of Invention of a National Stage Application. See MPEP §801 and 1850.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending.

Claims 5 , 6, 8-10, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-4, 7, 11-15, and 17-20 are examined herein.

Information Disclosure Statement

37 CFR §1.98(a)(ii) states any information disclosure statement filed under §1.97 shall include a column that provides a space, next to each document to be considered, for the examiner's initials. The IDS submitted 9/7/2006 does not comply with this rule. Nevertheless, the reference cited therein has been considered and for purposes of clarity has been cited in the accompanying PTO-892 form. Applicant is further reminded 37 CFR §1.98 requires each publication listed in an IDS be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

Specification/Sequence Compliance

The disclosure is objected to because of the following: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification as filed does not comply with the requirements above, in particular 1.821(d) at least, because it contains nucleotide sequences of over 10 nucleobases each that are not identified by accompanying sequence identifiers.

For example, nucleotide sequences are set forth in figures 2 and 13 without corresponding SEQ ID NO: identifiers. This is but a sampling of the many sequences set forth in the instant application without SEQ ID NO: identifiers. Applicants are advised to review the entire application—claims, drawings, and specification—for complete compliance with the Sequence Rules.

Thus, the Examiner notes herein that the above listing of pages and figures which set forth examples in the specification of nucleotide sequences that require SEQ ID NO: is by way of illustration. In order to be fully responsive to this Office Action, Applicant should review this application in its entirety to ensure compliance with the requirements of 37 CFR 1.821 through 1.825 and to make all appropriate corrections.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Claim Objections

Claims 4 and 14 are objected to for awkward wording: "at its either or both ends."

Claim 7 is objected to because it cannot because of the phrase "incorporated therein." The specific meaning of the phrase and what limitation(s) in the claim the phrase specifically modifies is unclear. Since the claim recites "A plasmid comprising the cassette construct according to claim 4," the phrase "incorporated therein" is superfluous, as the limitation "comprising" already requires the plasmid contain the cassette. Deleting the phrase "incorporated therein" would be remedial.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 11-15, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 13 are drawn to the cassette construct of claims 1 and 2, respectively, wherein either or both ends of the construct "are pretreated for target sequence binding." It is unclear what is meant by "pretreated for target sequence binding." Neither the claims nor the specification clearly inform one of skill as which act(s) are specifically included or excluded by the limitation, and there is no written description or explicit definition teaching one of skill what pretreating actually means or involves. The metes and bounds of the term "pretreated," and thereby the claims, are unclear since it cannot be determined how or in what manner the construct is to be pretreated such that it is ready for or capable of target sequence binding.

Because no reasonably definite interpretation can be made of the claims, the claims have not been further treated on the merits. Dependent claim 15 is rejected therefore.

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Claims 11, 12, and 17-19 are rejected as indefinite under 35 USC 112, second paragraph, because the claims depend from withdrawn claims, claims 5, 6, 8, and 9. Accordingly, the claims are incomplete (MPEP 608.01(n)). Amending the claims to define the vectors and host cells using product by process format (MPEP 2113) would be acceptable. The claims would then be examined to the extent they remain drawn to products within Group I. Presently, however, as the claims are not written in independent form, and no reasonable interpretation of the claims can be made without resorting to an examination of claims that are no longer under consideration in view of the restriction requirement, claims 11, 12, and 17-19 have not been further treated on the merits herein.

Claims 4 and 14 are rejected as indefinite under 35 USC 112, second paragraph, because of the recitation "which comprises a target sequence bound thereto at its either or both ends." There is no antecedent basis in the claims for "either or both ends." It is unclear which ends are being referred to. Claims 1 and 2 make no requirement as to the particular order of the adaptor and spacer elements recited in claim 1; thus, the identity and location of the ends referred to in claim 4 are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Sui et al. (2002) " A DNA vector-based RNAi technology to suppress gene expression in mammalian cells" *Proc. Natl. Acad. Sci* 99:5515-5520.

Claim interpretation:

In claim 1, it is unclear whether the phrase "consisting of" is intended to modify "A cassette construct for preparing..." or "a target sequence." Further, while the term "adaptor sequence" is interpreted in light of the definition at page 6 of the specification, there is no clear or limiting definition for the term "target sequence." The target sequence may be a chromosomal mRNA, tRNA, or ribosomal RNA sequence. The target sequence may be a translated or non-translated sequence. The target sequence may be the sequence in the construct or the sequence targeted by the construct. The target sequence may be nearly any nucleotide sequence targeted by any molecule, protein or nucleic acid.

Thus, claims 1, 2, 4, 7, and 15 are subject to alternative interpretations. For purposes of this rejection the claims require nothing more than a cassette construct for preparing an inverted repeat sequence of a target sequence, the target sequence consisting of an adaptor sequence, a spacer sequence, and an inverted repeat sequence of the adaptor sequence. In this embodiment, the limitation of claim 2 add no further patentable weight, as it modifies the target sequence and not the cassette.

The rejection:

Sui et al. disclosed a U6 promoter-driven expression cassette for cloning and expressing hairpin RNAs (Fig. 1, page 3). Absent evidence to the contrary, the U6-containing constructs disclosed by Sui et al. are constructs suitable for preparing an inverted repeat sequence having each of the elements recited in the claims.

***

Claims 1, 4, 7, 14, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brummell et al. (2003) "Inverted repeat of a heterologous 3'-untranslated region for high-efficiency, high-throughput gene silencing" *The Plant Journal* 33:793-800.

Interpretation:

For purposes of this rejection, the phrase "consisting of" in claim 1 is considered to modify the "cassette construct."

Rejection:

Brummel et al. taught an inverted repeat expression construct (Fig. 1, page 794) comprising an FMV promoter, a hsp70 leader sequence, a spacer sequence flanked by inverted repeats of the 3'-untranslated region of the *nos* gene (adaptor and inverted adaptor), and, at one end, the PG transgene (a target sequence). At page 798, left column, it is taught the construct was cloned into a SVS297 plasmid for transformation of plant cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
June 2, 2009

Notice to Comply	Application No.	Applicant(s)	
	10572750	DEMURA ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Nucleotide sequences in Figs. 2 and 13 set forth without SEQ ID NO identifiers.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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